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Filed : February 11, 2004

#### REMARKS

The foregoing amendments and the following remarks are responsive to the June 30, 2006 Office Action. Claims 31, 32, 34-50, 99-102 remain pending in the present application, Claims 31, 49, and 102 having been amended, Claims 33 and 103 having been canceled.

In response to the Office Action mailed June 30, 2006, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

#### Claim 101 Fully Complies With 35 U.S.C. § 112

Claim 101 was objected to, the Examiner maintaining that the claim is unclear. Claim 101 has been amended to make the claim more easily readable. Applicant further submits that the amendment made in response to the objection has not narrowed the claim language. Thus, all of the equivalents of the original recitations in the claim are also equivalents of the now recited recitations.

#### Gottesman Does Not Disclose the Irrigation Shield Recited By Claims 99-101

Claims 99-101 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Gottesman *et al.* (U.S. Patent No. 4,834,068) ("Gottesman"). Applicant respectfully traverses the present rejections.

Gottesman discloses a rigid, disk-shaped, shield for use during endoscopic procedures. The shield is disposed between a treating physician and the patient for procedures such as ureteroscopy, colonoscopy, bronchoscopy, and other procedures wherein a telescoping device is introduced to a bodily orifice. The shield is disclosed to have a "frame 40 made from wire, plastic, or any other suitable material." Gottesman, c. 3, Ins. 67-68. This is consistent with the illustrated embodiments shown in Gottesman Figures 1-3, wherein the shield has a frame sufficiently rigid to maintain the shape of the shield without support. Gottesman does not disclose the shield to be a **flexible sheet**.

By contrast, Claim 99 recites, "an irrigation shield comprising a **flexible sheet** having an elastically enlargeable aperture configured to releasably engage a head of an irrigation nozzle." (Emphasis added).

Thus, unlike Gottesman, Claim 99 is directed to an irrigation shield comprising a flexible sheet, in combination with the other recitations. The flexible sheet is useful, as described in the

present application in paragraphs 227 and 228, because medical personnel can adapt the sheet for use with irrigation of any of several portions of human anatomy. Unlike the shield of Gottesman, where the shield is merely imposed between the physician and bodily orifice, the flexible sheet permits medical personnel to cover the affected area completely, and the sheet can conform to different portions of the human anatomy, including a hip, leg, elbow, shoulder, or hand.

Therefore, Gottesman fails to disclose or suggest the irrigation shield recited by Claim 99. For at least this reason, Applicant respectfully requests the Examiner withdraw the rejection of Claim 99 and pass this Claim to allowance.

Additionally, Applicant submits that Claims 100 and 101 also define over the cited reference, not only because they depend from Claim 99, but also on their own merit. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of Claims 100 and 101 and pass these claims to allowance.

Holloway Does Not Disclose the Medical Basin Recited By Claim 103

Claim 103 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Holloway *et al.* (U.S. Patent No. 5,381,562) ("Holloway"). Applicant respectfully traverses the present rejections. However, Applicant has cancelled Claim 103 to expedite prosecution of the remaining Claims. Applicant expressly reserves the right to pursue Claim 103 through continuation practice.

The Irrigation Kit Recited by Claims 31, 33, 35-39, and 43-48 is Not Obvious Over McKinnon

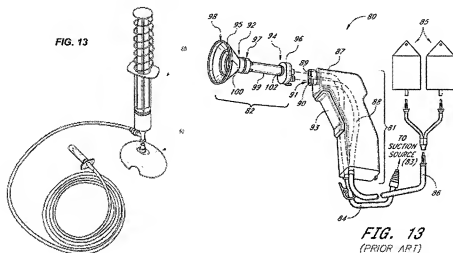
Claims 31, 33, 35-39, and 43-48 stand rejected under 35 U.S.C. § 103(a) as being obvious over McKinnon *et al.* (U.S. Patent No. 6,558,344) ("McKinnon"). Applicant respectfully traverses the present rejections.

*Claim 31*

McKinnon discloses a splash shield having a generally cup-like, oval shape. The shield is disclosed with and without side notches, but McKinnon does not disclose that the shield is flexible. Instead, the shield rigidly surrounds an irrigation device, confining splash from the irrigation region.

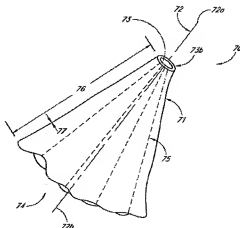
This shield is precisely the kind of splash shield identified as prior art in the present application. Firstly, this type of shield is illustrated in Figure 13 of the present Application.

As shown in the reproduction of Figure 13 of the present Application (below, right), this rigid splash shield 95 has a shape that is almost identical to the splash shield 10 of McKinnon, as shown in the reproduction of Figure 13 of McKinnon (below, left).



The present Application also explains how the flexible sheet now recited in Claim 31 can be used with this prior art type of splash shield 95. For example, the present Application indicates the following with reference to Figure 12, reproduced below:

[0226] During operation, medical personnel connect the handpiece 81 to the tip 82 and fit the rim 98 of the shield 95 through the aperture 73 in its enlarged state so that the elastic member 73b preferably rests around the collar 97. The elastic member 73b preferably generates a gripping force on the collar to substantially prevent the elastic member 73b from sliding along the collar 97. Personnel optionally shorten the length 76 of the sheet 71 as desired. For example, personnel can cut the sheet 71 a desired distance circumferentially around the axis 72. Medical personnel preferably cut the sheet 71 with scissors, but may optionally use any sharp object.



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McKinnon only teaches the "conical splash shield extending distally from a collar attached to a tip of the irrigation device" of Claim 31. McKinnon, however, completely fails to teach any **additional** flexible sheet that can fit over the conical splash shield.

By contrast, Claim 31 recites, an "irrigation kit comprising: a flexible sheet having an aperture configured to engage an irrigation device; and a basin for collecting irrigation fluid used during an irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material; wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device."

As noted above, the additional flexible sheet is advantageous over a splash shield because medical personnel can adapt the sheet to substantially completely cover any of several portions of human anatomy during irrigation by conforming, for example, to the shape of a limb, unlike a rigid splash shield. Additionally, the flexible sheet covers substantially the entire limb being irrigated, preventing the irrigating fluid from dispersing beyond the immediate vicinity of the irrigating device. Finally, because the flexible sheet recited in Claim 31 has an opening specifically designed to be able to fit over the type of conical shield taught by McKinnon, the flexible sheet of Claim 31 can be used in conjunction with this type of conical splash shield, a device commonly used in modern operating rooms.

Accordingly, Applicant submits that Claim 31 clearly and non-obviously defines over the cited references. Applicant also submits that Claims 32 and 34-48 also define over the cited references, not only because they depend from Claim 31, but also on their own merit.

The Irrigation Kit Recited by Claims 31, 32, 34 and 49-50 is Not Obvious Over Greco

Claims 31, 32, 34 and 49-50 stand rejected under 35 U.S.C. § 103(a) as being obvious over Greco (U.S. Patent No. 5,312,385) ("Greco"). Applicant respectfully traverses the present rejections.

However, in order to expedite prosecution of the present Application, Applicant has canceled Claim 33 (which was not rejected as being anticipated by Greco) and incorporated the subject matter thereof into Claim 31. Thus, the present rejection of Claims 31, 32, and 34 is now moot.

Additionally, Applicant has amended Claim 49 into independent form. With regard to Claim 49, Applicant would like to note that Greco teaches a splash shield and a funnel that can

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be used in conjunction with an irrigation basin. However, Greco fails to teach a basin with a convertible portion that is configured to transform the basin from a normal basin, to a basin that has an aperture in lower portion thereof, that can be used to drain the basin during an irrigation procedure.

Rather, the portion of the Greco disclosure identified by the Examiner merely indicates that the SPLASH SHIELD can have a hole in it; not the basin.

By contrast, Claim 49 now recites an "irrigation kit comprising: a flexible sheet having an aperture configured to engage an irrigation device; and a basin for collecting irrigation fluid used during an irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material; wherein the basin has at least one surface, said surface having at least one convertible portion configured to be convertible between a complete leak proof wall and an aperture configured to allow the basin to be drained through the aperture."

Greco has no disclosure whatsoever of a basin with such a convertible portion. Thus, Applicant submits that Claim 49 clearly and non-obviously defines over the Greco reference. Applicant also submits that Claim 50 also defines over the cited reference, not only because it depends from Claim 49, but also on its own merit.

The Applied Combination of McKinnon/Gottesman Does Not Make Obvious the Irrigation Kit Recited By Claims 40-42

Claims 40-42 stand rejected under 35 U.S.C. § 103(a) as unpatentable over McKinnon in view of Gottesman et al. Applicant respectfully traverses the present rejection.

However, firstly, Applicant submits that Claims 40-42 define over the cited references, not only because they depend from Claim 31, which Applicant submits is now allowable as noted above, but also on their own merit. Accordingly, Applicant respectfully request the Examiner withdraw the rejection of Claims 40-42 and pass these claims to allowance.

Gottesman Does Not Make Obvious the Irrigation Shield Recited By Claim 102

Claim 102 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Gottesman et al. Applicant respectfully traverses the present rejection.

However, Applicant submits that Claim 102 defines over the cited references, not only because it depends from Claim 99, which Applicant submits is now allowable as noted above,

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but also on its own merit. Accordingly, Applicant respectfully request the Examiner withdraw the rejection of Claim 102 and pass this claim to allowance.

SUMMARY

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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